

**REMARKS****I. PRELIMINARY REMARKS**

Claim 21 has been amended. Non-elected claims 11-20 and 31-34 have been canceled. No claims have been added. Claims 1-10 and 21-30 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

**A. Information Disclosure Statements Not Considered**

Applicant filed Information Disclosure Statements ("IDSs") prior to the mailing of the outstanding Office Actions on the following dates:

Jun. 12, 2001	Jan. 3, 2002	July 24, 2002	Apr. 12, 2003
Sep. 22, 2001	Feb. 16, 2002	Sep. 27, 2002	
Oct. 29, 2001	Apr. 20, 2002	Nov. 15, 2002	

Copies of the IDSs, including the PTO form 1449s and date stamped postcard receipts, are attached hereto as Exhibit 1. The Office Action does not include any indication that the IDSs have been considered. Accordingly, applicant hereby requests that the Examiner consider the IDSs, initial the PTO form 1449s (or SB08s) and return them to applicant with the next Office Action.

Applicant also notes that a number of additional IDSs (dated Aug. 23, 2203, Sep. 18, 2003 and Nov. 26, 2003) were filed subsequent to the mailing of the outstanding Office Action. Applicant hereby requests that the Examiner also consider these IDSs, initial the PTO form 1449s (or SB08s) and return them to applicant with the next Office Action.

**B. Statement of Rejections**

Applicants notes that the cited references together include well over one hundred and fifty (150) Figures, countless reference numerals and almost seventy (70) columns

of text to illustrate and describe a myriad of different medical devices. Nevertheless, the statements of rejection in the Office Action do not include a single reference to a particular Figure, reference numeral, or section of text by column and line number. Accordingly, the remarks below are based on applicant's "best guess" as to which portions of the cited references formed the basis for the rejections. Applicant hereby requests that, should the Examiner maintain the present rejections or make new rejections in a subsequent Office Action, specific Figure numbers, reference numerals, and/or sections of text be identified.

## II. BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to steerable loop structures. Referring to Figure 1, a formal version of which is reproduced below for the Examiner's convenience, a catheter 10 in accordance with one embodiment of a present invention is shown being used in combination with a sheath 22. The catheter 10 includes a catheter body 12 that extends through the sheath 22. The proximal end of the catheter body 12 is secured to a handle 16. A pull wire 26 extends from the distal end of the catheter body 12 proximally along the *exterior* of the catheter body to a handle 28. The pull wire 26 may be used to pull the distal portion of the catheter body into a loop structure 30. The exemplary embodiment also includes a pair of steering wires 52a and 52b that are connected to the distal portion of the elongate body 12. The steering wires 52a and 52b extend through the *interior* of the catheter body 12 to a lever 60 on the handle 16.

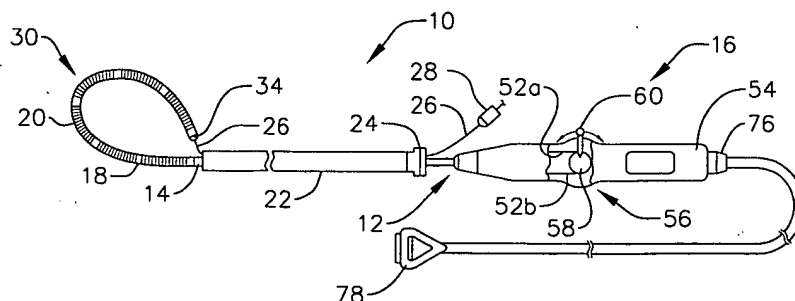
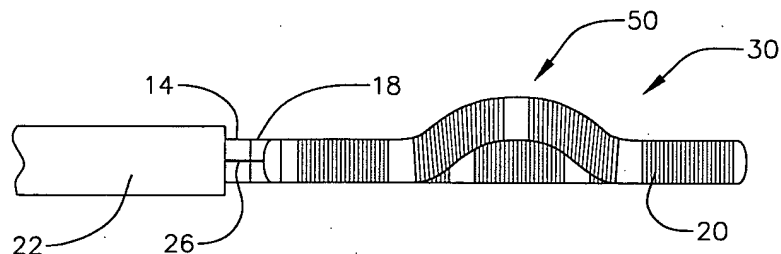


Figure 1 of the Present Application

Turning to Figure 6 of the present application, a formal version of which is reproduced below for the Examiner's convenience, the steering wires 52a and 52b may be used to deflect a portion 50 of the loop structure 30 out of the loop structure plane in order to improve contact between the electrodes 20 and tissue. [See also the specification page 10, line 22 to page 11, line 8.]



**Figure 6 of the Present Application**

### **III. PRIOR ART REJECTIONS**

#### **A. The Rejections**

Claims 1-4, 8-10, 21-23, 29 and 30 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,332,880 to Yang ("the Yang '880 patent"). Claims 5-7 and 24-27 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Yang '880 patent and U.S. Patent No. 6,048,329 to Thompson ("the Thompson '329 patent"). The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

#### **B. Apparent Errors And Omissions In The Statements Of Rejection**

The statements of rejection on page 3 of the Office Action appear to include at least one error and at least one omission. First, with respect to the rejection under 35 U.S.C. § 103, the statement of rejection indicates that claim 4 has been rejected. In view of the fact that claim 4 was also rejected under 35 U.S.C. § 102, applicant has

assumed for the purposes of this response that the reference to claim 4 in the statement of rejection under 35 U.S.C. § 103 was in error and that claim 4 has been rejected under 35 U.S.C. § 102. Turning to claim 28, the statements of rejection do not mention claim 28. Accordingly, applicant has assumed for the purposes of this response that claim 28 has not been rejected. Should this assumption be in error, applicant hereby requests that the Examiner clarify the status of claim 28 in a supplemental, non-final Office Action.

### C. Discussion With Respect To Claims 1-4 And 8-10

Independent claim 1 calls for a combination of elements comprising “an elongate body,” “at least one operative element supported on the distal region of the elongate body,” “a control element defining a distal portion associated with the distal end of the elongate body and a proximal portion ***extending along the exterior of the elongate body*** toward the proximal region of the elongate body” and “a steering element secured to the distal portion of the elongate body and ***extending within the interior of the elongate body*** to the proximal region of the elongate body.” The cited reference fails to teach or suggest such a combination.

For example, referring to Figure 17A and column 14, lines 42-57, the Yang ‘880 patent discloses an apparatus in which a catheter tube 12 extends through a sheath 102. A plurality of electrodes 28 are supported on the distal region of the catheter tube 12. A pull wire 106 extends from the distal end of the catheter tube 12 and along the exterior of the catheter tube to a stop/handle 118. The pull wire may be used to pull the distal portion of the catheter tube 12 into a loop structure 100. In contrast to the claimed combination of elements, the apparatus illustrated in Figure 17A does not include a “a steering element secured to the distal portion of the elongate body and ***extending within the interior of the elongate body*** to the proximal region of the elongate body.”

Turning to the Figure 66 and column 30, line 26 to column 31, line 4, the Yang ‘880 patent discloses an apparatus including a catheter tube 454 that extends through a sheath 472. A pair of steering wires 464 extend through the interior of the catheter tube

454 to a knob 468 on the handle 256. Instead of having the pull wire 106 (Figure 17A) form the loop, the distal end 470 of the catheter tube 454 may be secured to the distal end 476 of the sheath 472. A loop is formed by urging the catheter tube 454 distally relative to the sheath, which causes a portion of the catheter tube to bulge out of the slot 474 in the sheath 472. Thus, in contrast to the combination defined by independent claim 1, there is no "control element ... **extending along the exterior of the elongate body** toward the proximal region of the elongate body" in the apparatus illustrated in Figure 66.

As the Yang '880 patent fails to teach or suggest each and every element of the combination recited in independent claim 1, applicant respectfully submits that claims 1-4 and 8-10 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

#### **D. Discussion With Respect To Claims 5-7**

Applicant respectfully submits that the Thompson '329 patent fails to teach or suggest anything that would remedy the above-identified deficiencies in the Yang '880 patent with respect to independent claim 1. As such, claims 5-7 are patentable for at least the same reasons as independent claim 1 and the rejection of claims 5-7 under 35 U.S.C. § 103 should be withdrawn.

#### **E. Discussion With Respect to Claims 21-23, 29 And 30**

Independent claim 21 calls for a combination of elements comprising "an elongate body," "a loop structure associated with the distal region of the elongate body and defining an interior and a loop structure plane," "at least one operative element supported on the loop structure" and "a steering element **extending through the interior of the loop structure** and the interior of the elongate body to the proximal region of the elongate body, the steering element being **secured to the loop structure such that proximal movement of the steering element will bend a portion of the**

***loop structure out of the loop structure plane and leave the remainder of the loop structure in the loop structure plane.***” The cited reference fails to teach or suggest such a combination.

The Yang ‘880 patent discloses various apparatus that include out of plane bending caused by a proximally moving device. Referring to Figures 25-42B, for example, the Yang ‘880 patent discloses a variety of devices which include loop structures that are supported on the distal end of the catheter tube 12. The loop structures are formed and bent by various combinations of spline elements and wires. In contrast to the combination of elements defined by independent claim 21, the devices which bend the spline elements that form the loops do not extend through the interior of those spline elements.

As the Yang ‘880 patent fails to teach or suggest each and every element of the combination recited in independent claim 21, applicant respectfully submits that claims 21-23, 29 and 30 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

#### **F. Discussion With Respect to Claims 24-27**

Applicant respectfully submits that the Thompson ‘329 patent fails to teach or suggest anything that would remedy the above-identified deficiencies in the Yang ‘880 patent with respect to independent claim 21. As such, claims 24-27 are patentable for at least the same reasons as independent claim 21 and the rejection of claims 24-27 under 35 U.S.C. § 103 should be withdrawn.

#### **IV. CLOSING REMARKS**

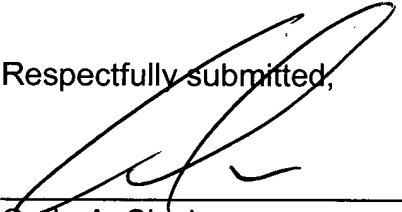
In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

12/22/03  
Date

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Respectfully submitted,  
  
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